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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/595,195   | 06/16/2000  | Sanjay Nigam         | SD9-141-2           | 1117             |
| 41790  | 7590        | 11/01/2005           | EXAMINER            |                  |
| BUCHANAN INGERSOLL LLP<br>(INCLUDING BURNS, DOANE, SWECKER & MATHIS)<br>12230 EL CAMINO REAL<br>SUITE 300<br>SAN DIEGO, CA 92130 |             |                      | FORD, ALLISON M     |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1651                |                  |
| DATE MAILED: 11/01/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/595,195

Applicant(s)

NIGAM ET AL.

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 8, 9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments/Amendments*

Applicant's response filed 1 August 2005 have been received. Amendments to claims 1 and 10 have been entered. Claim 6 has been cancelled, claims 1-5 and 7-12 remain pending in the current application, with claims 2-4, 8-9, and 11 being withdrawn from consideration. Claims 1, 5, 7, 10 and 12 have been considered on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-7, 10, and 12 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 to delete the word "the" from the 28<sup>th</sup> line of the claim (previously read: "wherein **the** at least one growth factor comprises glial cell line-derived neurotrophic factor (GDNF)."). It appears applicant intends for GDNF to be 'the at least one growth factor' used to culture the individual branch tip buds in step (a) and the mesenchyme in step (b); however, by removing the adjective "the" it reads as a statement of fact ("at least one growth factor is GDNF") instead of a limitation of the aforementioned 'at least one growth factor' of the prior steps.

Applicant's claim 7 is further rejected because it is unclear which matrix is being referenced by the limitation "the matrix," claim 1 describes *an extracellular matrix* in step (a) and *a matrix* in step (c).

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5-7 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Qiao et al (Proc. Natl. Acad. Sci, 22 June 1999).

Applicant's claims are drawn to a method for constructing a mammalian tissue or a fragment thereof in vitro, comprising (a) culturing and propagating embryonic epithelial-derived explants, tissue or cells, comprising isolating the tissues or cells and growing them in culture, permitting the tissues or cells to form multiple branches, dissecting out individual branch tips, culturing the individual branch tips in the presence of nutrient medium, serum, at least one growth factor, and BSN-conditioned medium (BSN-CM) on an extracellular matrix (ECM) gel for several generations to generate branch tip buds; (b) culturing and propagating isolated embryonic or fetal metanephric mesenchyme comprising dissecting out embryonic or fetal metanephric mesenchyme at the time of induction, culturing the embryonic or fetal metanephric mesenchymal tissue in the presence of nutrient medium, serum, at least one growth factor, and BSN-CM, partitioning mesenchyme into multiple pieces and culturing each piece separately, and inducing vasculogenesis by subjecting cultured mesenchyme to substrate deprivation or addition of soluble growth factors to produce vascularized mesenchyme; (c) combining each vascularized mesenchyme with each cultured branch tip bud in a matrix in which in vitro angiogenesis has begun by co-culturing the vascularized mesenchyme and the cultured branch tip buds; and (d) culturing the combined tissue under conditions to ensure continued cell growth to obtain a vascularized mammalian tissue; wherein the at least one growth factor is glial derived neurotrophic factor (GDNF). Claim 5 requires the at least one growth factor to further comprise at least one other growth factor selected from

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the group consisting of EGF, HGF, IFG, and FGF-2. Claim 7 requires the matrix on which the vascularized mesenchyme and the cultured branch tip buds are co-cultured to comprise a mixture of type I collagen and a basement membrane preparation. Claim 12 requires the vascularized mammalian tissue to be mammalian kidney tissue.

Qiao et al teach a method for forming vascularized mammalian kidney tissue in vitro comprising isolating and culturing uterine buds dissected from embryonic mesenchyme (which applicant calls epithelial-derived explants) on an ECM gel comprised of type I collagen and Matrigel in the presence of nutrient medium, fetal calf serum, BSN-CM, and a growth factors mix comprising GDNF, EGF, HGF, IGF and FGF-2, for several generations to generate branch tip buds; then combining individual branch tip buds with cultured embryonic metanephric mesenchyme on a transfilter and co-culturing the combined tissue under conditions ensuring continued cell growth (See Qiao et al, Pg. 7331, col. 2- Pg. 7332, col. 1& Pg. 7334, col. 2) (Claims 1, 5, 7 and 12). Therefore the reference anticipates the claimed subject matter.

### ***Double Patenting***

Claims 1 and 12 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 29, and 38 of copending Application No. 10/608,783. The method of claims 26, 29 and 38 of copending application 10/608,783 are directed to a method of culturing uterine bud cells and metanephric mesenchyme cells in a BSN cell conditioned medium, and then allowing the cells to interact to stimulate branching tubular morphogenesis. Although the conflicting claims are not identical, they are not patentably distinct from each other because both methods require culture of uterine bud cells and metanephric mesenchyme in BSN cell conditioned medium and then subsequent interaction of the two cell types to form a vascularized mammalian kidney tissue. Though the copending claims do not require the particular culturing steps of the uterine bud cells or metanephric mesenchyme that are claimed in steps (a) and (b) of the current application, the culturing

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steps (a) and (b) appear to be obvious culture steps for propagation of the cell types, and would be obvious to one of ordinary skill in the art; therefore both methods effectively claim the same method of forming the vascularized mammalian kidney tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

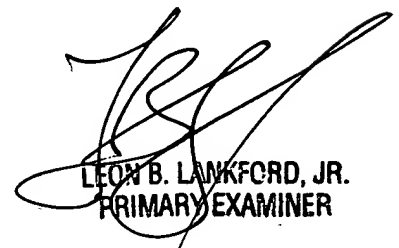
### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford  
Examiner  
Art Unit 1651

  
LEON B. LANKFORD, JR.  
PRIMARY EXAMINER